

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION))))	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 03-10643-PBS
THIS DOCUMENT RELATES TO: <i>The City of New York, et al.</i> v. <i>Abbott Laboratories, et al.</i>)))))))	Judge Patti B. Saris

**PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT ON ISSUES RELATING TO THE FEDERAL
UPPER LIMIT AND UNDER NEW YORK SOCIAL SERVICES LAW § 145-B**

INTRODUCTION

Defendants take the legally unsupportable position that the question before this Court with respect to plaintiffs' FUL claims is not whether defendants systematically attempted to and did obtain artificially inflated payment on behalf of themselves or others by the creation of a fictional alternative universe of false price arrays, but whether, having forced CMS to choose among artificially inflated prices, defendants can be held accountable for damages. This insidious proposition makes no contact with N.Y. Soc. Serv. L. § 145-b ("Section 145-b"). Section 145-b punishes even the attempt to defraud. *See* Section 145-b(1)(a), as this Court made crystal clear during the exchange with

counsel for defendant Sandoz cited below and featured in plaintiffs' opposition to defendants' Daubert motion.¹

Although Section 145-b explicitly imposes damages for failed attempts, defendants' attempts here did not fail. They succeeded in causing great injury. CMS has testified that, had defendants reported alternative true WACs, those would have been considered when setting FULs, and the FULS likely would have been lower. *See* Declaration of Susan E. Gaston, dated June 15, 2009 ("Gaston Decl.") at ¶¶ 7, 10, 12 (Exhibit C to the Affidavit of Joanne M. Cicala in Opposition to Defendants' Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims ("Cicala Aff.") [Dkt. No. 6144]).

¹ The Court: But you're saying, if everyone lies, everyone's off the hook?

Mr. Cross: No. The people who set the FUL. She [Plaintiffs' counsel Joanne M. Cicala] has to plead who set the FUL. If my client didn't set the FUL because my WAC was higher than Mylan's WAC, I've got nothing to do with the transaction.

The Court: Unless you lied.

Hearing Transcript dated May 16, 2007 at 33:14-20 (attached as Exhibit A to the Affidavit of Kathryn B. Allen, sworn to June 30, 2009 and submitted in opposition to defendants' joint motion to exclude expert report and testimony of Harris L. Devor, CPA ("Allen Aff.")).

ARGUMENT

I. **DEFENDANTS' ACTIONS ARE SUFFICIENT TO CREATE LIABILITY UNDER SECTION 145-B**

A.

To secure partial summary judgment under N.Y. Social Services Law § 145-b (“Section 145-b”), plaintiffs need show only an absence of material controversy surrounding defendants’ incessant attempts to obtain artificially inflated payments. *See* plaintiffs’ memorandum of law in support of their motion for partial summary (“Pl. FUL Br.”) at 14-18. The issue of knowledge, therefore, is reduced to whether millions of uninterrupted attempts to obtain inflated payments can be regarded as inadvertent. The proposition is rhetorical, because the conclusion is undeniable. Plaintiffs have presented the Court with (a) alternative true WACs based on defendants’ own data for every drug at issue²; (b) testimony from CMS averring that the alternative true WACs would have been considered had they been reported and that the FULs likely would have been less^{3, 4}; (c) incontrovertible evidence that the FUL Thirteen knew their WACs did not represent

² *See* Exhibit B to the Declaration of Harris L. Devor in Support of Plaintiffs’ Motion for Partial Summary Judgment on Issues Relating to the Federal Upper Limit and Under New York Social Services Law § 145-b, dated May 15, 2009 (“Devor Decl.”) [Dkt. No. 6061].

³ *See* Gaston Decl. at ¶¶ 7, 10, 12.

⁴ CMS has testified that it rejected the “outliers”. *See* Gaston Decl. at ¶ 4. Defendants cannot seriously argue that if CMS had been presented with an array of prices between \$10 and \$50 for a drug it would have set the same FUL as if it had been presented with a greater range. By way of example, Ms. Gaston testified that had she been given the WACs that Mr. Devor calculated for Teva Pharmaceuticals USA, Inc., Geneva Pharmaceuticals, Inc., Watson Pharmaceuticals, and Mylan Pharmaceuticals, Inc. for metoprolol tartrate in 2001, using her usual methodology she would likely have established a FUL at \$0.0672 rather than the \$0.0914 FUL that was established. *See* Gaston Decl. at 10.

actual prices^{5, 6}; (d) incontrovertible evidence that the FUL Thirteen knew or were legally obliged to know their false WACs would be used by Medicaid for reimbursement purposes⁷.

Notably, defendants do not supply a single stitch of record evidence to support the veracity of their WACs or other published prices. They present no WAC List Price Test results or AWP spread test results. Their expert, Sumanth Addanki, presented both in the MDL Track One class trial when opining about the accuracy of Schering's WACs for the brand drug Proventil. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp.

⁵ See, e.g., Plaintiffs' Memorandum of Law in Support of Their Motion for Partial Summary Judgment ("Pl. FUL Br.") at n.13 [Dkt. No. 6077]; Appendix A to Pl. FUL Br.; Barr 56.1 [Dkt. No. 6062] at ¶¶ 26-27; Dey 56.1 [Dkt. No. 6063] at ¶¶ 21, 23; Ethex 56.1 [Dkt. No. 6064] at ¶¶ 22, 24, 29; Ivax 56.1 [Dkt. No. 6065] at ¶¶ 19; Mylan 56.1 [Dkt. No. 6066] at ¶¶ 20, 23, 25; Par 56.1 [Dkt. No. 6067] at ¶¶ 20-21; Purepac 56.1 [Dkt. No. 6068] at ¶¶ 23-24, 29; Roxane 56.1 [Dkt. No. 6069] at ¶¶ 12; Sandoz 56.1 [Dkt. No. 6070] at ¶¶ 34, 39-43; Teva 56.1 [Dkt. No. 6071] at ¶¶ 25-26; Watson 56.1 [Dkt. No. 6073] at ¶¶ 21; Wyeth 56.1 [Dkt. No. 6074] at ¶¶ 19-21, 23; Declaration of Harris L. Devor, dated May 15, 2009, and submitted in support of plaintiffs' motion ("Devor Decl.") [Dkt. No. 6061].

⁶ This Court has already ruled in the Track One Trial that published prices must "reflect[] the price that most people paid":

when discounting became so prevalent that the list price no longer reflected the price that most people paid, it became unfair and deceptive to continue publishing such a list price upon which the AWP is based. See 16 C.F.R. § 233.3(a) ("To the extent that list or suggested retail prices do not in fact correspond to prices at which a substantial number of sales of the article in question are made, the advertisement of a reduction may mislead the consumer.").

Track One Trial, 491 F. Supp. 2d at 105.

⁷ See, e.g., Pl. FUL Br. at n.13; Appendix A to Pl. FUL Br.; Barr 56.1 at ¶ 16; Dey 56.1 at ¶ 10; Ethex 56.1 at ¶¶ 13-14; Ivax 56.1 at ¶ 7; Mylan 56.1 at ¶ 6; Par 56.1 at ¶ 6; Purepac 56.1 at ¶¶ 5-6; Sandoz 56.1 at ¶ 22; Teva 56.1 at ¶ 6; Schering-Warrick 56.1 at ¶ 17; Watson 56.1 at ¶ 8; *Commonwealth of Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008).

2d 20 (D. Mass. 2007) (“*Track One Trial*”); declaration of Sumanth Addanki from Track One Trial, filed December 1, 2006 [Dkt. No. 3430]. Dr. Addanki did likewise in the context of the Schering (brand drug) motion for a protective order. *See* Schering’s motion for a protective order, filed May 13, 2008 [Dkt. No. 5296] and affidavit of Sumanth Addanki, dated February 21, 2008, in support [Dkt. No. 5299]. These tests were not performed here because defendants know all NDCs would fail both.

The record evidence thus establishes defendants’ violations of Section 145-b. Defendants attempted to obtain payment of public funds by causing prices to be published that they knew were not tethered to actual prices. The attempt to obtain inflated Medicaid reimbursements is a *per se* wrong. *See, e.g., In re Pharm. Indus. Avg. Wholesale Price Litig.*, 2007 WL 1051642, at *11 (D. Mass. April 2, 2007) (“*NY Counties I*”) (agreeing that “defendants received public funds within the meaning of the statute when they fraudulently manipulated wholesale prices in order to increase Medicaid reimbursements to providers.”); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 2004 WL 2387125, at *2 (D. Mass. Oct. 26, 2004) (“*Suffolk II*”) (upholding Section 145-b claims against certain defendants); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 339 F. Supp. 2d 165, 179 (D. Mass. 2004) (“*Suffolk I*”).

Defendants’ response at once ignores the law, the law of this case and is absurd. Defendants admit that Section 145-b punishes even the attempt for payment (*See* FUL Defendants’ Joint Response in Opposition to Plaintiffs’ Motion for Partial Summary Judgment (“FUL Thirteen Opp.”) at 13-14) but now contrive to argue, with no support

whatsoever, that where defendants' lie is to a third party, rather than the state directly, the "attempt" language of Section 145-b does not apply and the lie must serve as the "actual" basis for the claim. The express language of the statute is contra and, besides, defendants can no longer contend that deceptions to any "third party" (defendants leave murky whether they are referring to CMS or the publishers or someone else, *see* FUL Thirteen Opp. at 13) absolves them from liability under Section 145-b.⁸ This Court has already held that publication to the publishing compendia has the same effect as reporting to government.⁹ And given that defendants have only one WAC or AWP at a time¹⁰, and

⁸ Defendants argue that when false statements are made to third parties, as opposed to the state, the "attempted" false statement must serve as the basis on which the actual claim was made. They claim that there is a distinction between false statements made to the state in connection with claims for payment and false statements to third parties, however, they fail to quote the entire section which reveals their argument is baseless:

For purposes of this section, "statement or representation" includes, but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, ***financial information whether in a cost report or otherwise***, health care services available or rendered, and the qualifications of a person that is or has rendered health care services.

See Section 145-b(1)(b) (emphasis added). Defendants have provided false financial information that subjects them to liability under this section. Perhaps more important, the argument would contravene this Court's prior holding that the plaintiffs may bring claims under Section 145-b notwithstanding that the injuries inflicted and benefits obtained pass through intermediaries. *See* n. 9, *infra*.

⁹ *See Suffolk I*, 339 F. Supp. 2d at 179 (where this Court determined that defendants did not have to make a false claim directly to the government for liability under Section 145-b to attach; defendants' false statements to publishing companies that were the basis for the providers' false claims was sufficient).

¹⁰ Barr 56.1 at ¶ 11; Ethex 56.1 at ¶ 11; Par 56.1 at ¶ 7; Purepac 56.1 at ¶¶ 10-11; Roxane 56.1 at ¶ 5; Sandoz 56.1 at ¶ 20; Teva 56.1 at ¶ 8; Schering-Warrick 56.1 at ¶ 8.

report the same one to all compendia¹¹, and know that Medicaid, like all third party payors, uses the same fictional prices as a basis for Medicaid reimbursement¹², a false AWP or WAC whether to CMS or to a publisher is equally actionable as a false AWP or WAC to New York Medicaid or any other State.¹³

Furthermore, Section 145-b is a remedial statute. Remedial statutes are broadly read. *See, e.g., In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (“the FCA is a remedial statute that must be broadly read”), citing *United States v. Neifert-White*, 390 U.S. 228, 232 (1968) (stating that the FCA should be read broadly because it is “intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.”).

Previous briefs on this very round of motions have shown how defendants miss the mark on exculpatory target knowledge. Defendants insist that CMS and New York Medicaid knew much more than the record evidence shows and that defendants knew much less. The argument essentially is this: CMS knew defendants’ published WACs were entirely false and inflated, yet set FULs on them anyway. New York Medicaid

¹¹ Barr 56.1 at ¶ 9, 12; Dey 56.1 at ¶ 15; Ethex 56.1 at ¶ 8; Purepac 56.1 at ¶ 11; Roxane 56.1 at ¶ 5; Sandoz 56.1 at ¶ 17; Teva 56.1 at ¶ 17-18; Wyeth 56.1 at ¶ 11.

¹² Barr 56.1 at ¶ 16; Dey 56.1 at ¶¶ 5, 10; Ethex 56.1 at ¶¶ 13-14; Ivax 56.1 at ¶¶ 7, 38; Mylan 56.1 at ¶ 6; Par 56.1 at ¶ 6; Purepac 56.1 at ¶ 5; Sandoz 56.1 at ¶¶ 21-23; Teva 56.1 at ¶¶ 6-7; Schering-Warrick 56.1 at ¶¶ 6, 16; Watson 56.1 at ¶ 8; Wyeth 56.1 at ¶¶ 13-14.

¹³ The liability is rooted in venerable doctrine that having placed false data into the public arena defendants are liable for all foreseeable harm given that defendants knew or should have known that CMS and State Medicaid programs would consider or use the false data. *See, e.g., Glanzer v. Shepard*, 233 N.Y. 236, 238-39, 135 N.E. 275 (N.Y. 1922) (defendant issuing a false certificate to one party knowing it will be used by a second party is liable for the consequences when the second party relies on the false statement).

knew likewise. Defendants, on the other hand, had no idea that when Medicaid used WACs to estimate EAC or to set the FUL, it actually believed in the integrity of defendants' data. Stated otherwise, defendants' proposition is that, surely Medicaid knew full well that defendants' data has been systematically inflated by more than 30%.

Although now legally irrelevant, the following background drives home the point. There is absolutely no record evidence anywhere that CMS or New York Medicaid knew or expected defendants to engage in the sort of secret deep discounting that resulted in the mega-spreads uncovered by these lawsuits. *See* Pl. FUL Opp. at 5-6, 11, 14. Even the evidence cited by defendants on this point supports plaintiffs' argument. The Federal Register on which defendants rely reveals that CMS was concerned that setting the FUL on defendants' published prices may not capture all potential cost savings because "our policy of using published prices as a basis for determining payment levels may cause *wholesalers* to invent new ways of offering discounts... The drawback is that neither State programs nor the Federal Medicaid program will benefit from such reductions in *wholesale* prices." FUL Thirteen Opp. at 7-8, citing 52 Fed. Reg. 28,648, 28,656 (July 31, 1987) (emphasis added). Critically, CMS was not concerned that *drug manufacturers* would invent new ways of offering discounts that Medicaid would miss out on. Why? Because any discounts offered by drug manufacturers would, by law (in theory at least), be reflected in the drug manufacturers' published prices. *Wholesaler* discounts, on the other hand, would *not* be reflected in the drug manufacturers' reported prices. That was CMS's concern. The fact that CMS was willing to set FULs on manufacturers' published

prices, knowing that in doing so it may not be taking advantage of discounts offered by *wholesalers*, does not mean that CMS was willing to accept false published prices from the manufacturers.¹⁴ Similarly, the fact that during for most if not all of the relevant time period every State's reimbursement formula was either WAC + x% or AWP-x% firmly establishes that every State Medicaid program believed that the EAC (at which the States were indisputably by law required to reimburse) was within that range.

Defendants point to the fact that CMS had AMPs. Indeed it did. But AMPs are not WACs. AMPs are indisputably average prices to a subset of customers (retailers). *See* 42 U.S.C. § 1396-r-8(k)(1)(A). WAC is indisputably wholesale acquisition cost. Defendants have presented no record evidence whatsoever as to what AMPs say about their WACs. More important, defendants have presented no record evidence as to what CMS knew or should have known what the AMPs would reveal. Further, AMPs are also not published and, therefore, by law, could not be used to set the FUL. *See* 42 C.F.R. § 447.332 (2005) (FUL "equal to 150 percent of the *published price* for the least costly therapeutic equivalent") (emphasis added). AMPs were required (at defendants' insistence) to be kept confidential (*see* 42 U.S.C. 1396r-8(b)(3)(D)) and could not be used for reimbursement (*see* Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008)).

¹⁴ In 1987 when the FUL was set CMS believed that published prices for generic drugs were inflated in the same 20-25% range as brands. *See* Medicare and Medicaid Programs: Limits on Payment for Drugs, 51 Fed. Reg. 29,560 (Aug. 19, 1986).

This entire line of defense is entirely at odds with black letter principles that defendants, seeking payment for their products from the public fisc, and having voluntarily signed the Medicaid rebate agreements, were obligated as a matter of law to familiarize themselves with the law and “turn square corners”. *See Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984); *Commonwealth of Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008).

B.

What AMPS do reveal is that, unsurprisingly, defendants have always had the ability to calculate and report accurate actual prices when they want to. In the case of AMPs, defendants calculate accurate (presumably) actual prices to be “paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.” *See* 42 U.S.C. § 1396r-8(k)(1)(A). Likewise, defendants could have calculated and published accurate WACs. Notably, defendants never argue otherwise. All they do is argue for an improper burden shift.

This Court has already ruled that the burden to discover defendants’ fraud should not be on the shoulders of the government.

While the government had the lawful authority to conduct surveys to determine actual provider costs and did not do so, there was no persuasive evidence in this record that the government actually knew about, or approved, the mega-spreads between the published prices and the true average provider acquisition costs. The lack of effective government oversight does not excuse defendants' conduct.

In re Pharm. Indus. Avg. Wholesale Price Litig., 520 F. Supp. 2d 267, 272 (D. Mass. 2007).

Finally, the record evidence shows what defendants knew. Defendants knew that State Medicaid agencies reimbursed on AWP, WAC and FUL.¹⁵ They knew that New York Medicaid reimbursed at FUL when a FUL was in place.¹⁶ They knew or should have known that the federal regulations required all Medicaid pharmacy reimbursements to be at EAC.¹⁷ They knew that CMS considered published prices when setting a FUL.¹⁸ Defendants knew that to market their products they had to present their customers with materials showing the spread between actual price and reimbursement price, be it FUL/MAC or AWP or WAC.¹⁹ They knew that the AWP's and WAC's they reported were not tethered to actual prices and were wildly inflated.²⁰ This is sufficient to satisfy the “knowing” prong of Section 145-b.

¹⁵ Barr 56.1 at ¶¶ 14-16; Dey 56.1 at ¶¶ 5, 10, 16; Ethex 56.1 at ¶¶ 13-14; Ivax 56.1 at ¶¶ 7, 38; Mylan 56.1 at ¶¶ 6, 14; Par 56.1 at ¶ 6; Purepac 56.1 at ¶ 5; Sandoz 56.1 at ¶¶ 21-23; Teva 56.1 at ¶ 6; Schering-Warrick 56.1 at ¶¶ 6-16; Watson 56.1 at ¶ 8; Wyeth 56.1 at ¶¶ 13-14.

¹⁶ Barr 56.1 at ¶ 1; Dey 56.1 at ¶¶ 1, 16; Ethex 56.1 at ¶¶ 1, 13; Ivax 56.1 at ¶¶ 1, 7, 38; Mylan 56.1 at ¶¶ 1, 6, 14; Par 56.1 at ¶¶ 1, 28; Purepac 56.1 at ¶ 1; Roxane 56.1 at ¶ 1; Sandoz 56.1 at ¶ 1; Teva 56.1 at ¶¶ 1, 7; Schering-Warrick 56.1 at ¶ 1; Watson 56.1 at ¶ 1; Wyeth 56.1 at ¶ 1. *See also* N.Y. Soc. Serv. L. § 367-a(9)(b)(i) (McKinney 2005).

¹⁷ *See* 42 C.F.R. 447.331 (2005); *Mylan*, 608 F. Supp. 2d at 132, 154.

¹⁸ Barr 56.1 at ¶ 17; Dey 56.1 at ¶ 16; Ethex 56.1 at ¶ 15; Ivax 56.1 at ¶ 38; Mylan 56.1 at ¶ 14; Par 56.1 at ¶ 17; Sandoz 56.1 at ¶ 23; Teva 56.1 at ¶¶ 6-7; Wyeth 56.1 at ¶ 14.

¹⁹ Barr 56.1 at ¶ 31; Ethex 56.1 at ¶¶ 32-33; Ivax 56.1 at ¶¶ 31-34; Mylan 56.1 at ¶¶ 27-28; Par 56.1 at ¶¶ 25, 27-28; Purepac 56.1 at ¶ 35; Sandoz 56.1 at ¶ 47; Teva 56.1 at ¶¶ 29-31; Watson 56.1 at ¶ 22; Wyeth 56.1 at ¶ 28.

²⁰ Barr 56.1 at ¶¶ 18, 23; Dey 56.1 at ¶¶ 17, 20-23; Ethex 56.1 at ¶¶ 16, 22-29; Ivax 56.1 at ¶¶ 18-19; Mylan 56.1 at ¶¶ 19-25; Par 56.1 at ¶¶ 18, 21-22; Purepac 56.1 at ¶¶ 16-17, 22-

C.

Defendants ask the Court to reject the materiality standard established in *Mylan* which “focuses on the potential effect of the false statement when it is made, not on the actual effect of the statement when it is discovered.” *Id.* at 153. However, this is the exact premise of Section 145-b, which attaches liability to even an “attempt” to obtain payment from the government, regardless of whether the claim is successful. *See* Section 145-b(1)(a). Then, in somewhat tortured logic, defendants present several cases that they say are not like the instant case as support for the proposition that their false claims are not material. *See* FUL Thirteen Opp. at 15-16. Plaintiffs agree that the cited cases are not like the instant case. They are all factually distinct.²¹ Furthermore, they stand for the

30; Roxane 56.1 at ¶¶ 9-16; Sandoz 56.1 at ¶¶ 34-36, 39-43; Teva 56.1 at ¶¶ 22, 25-26; Schering-Warrick 56.1 at ¶ 17; Watson 56.1 at ¶¶ 18-21; Wyeth 56.1 at ¶¶ 16-21, 23.

²¹ For example, in *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151 (D. Mass. 2004), Harvard and two employees were involved in a government-sponsored project that barred certain behavior; when the employees allegedly engaged in the behavior and knowingly caused documents to be submitted falsely certifying that Harvard was complying with the terms of the contract, they violated the FCA. *See id.* at 159-61. The court rejected Harvard’s argument that “not only must it have known that the claims were false, and that this falsity must have been material, but also that Harvard must have known the falsity was material.” *Id.* at 191. Rather, the court ruled that “[s]ince Harvard made a false certification, the government’s burden is not to prove that Harvard knew that [the government] would terminate the Project, but simply that it [Harvard] knew its claims were false.” *Id.*

In *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003), a government contractor was sued for allegedly falsely certifying to the government that no organizational conflicts of interest existed between contractor and subcontractor relating to a proposed government subcontract. *See id.* at 910-11. The court rejected the idea that the false statement must actually affect the government’s decision to fund the subcontract, ruling that a government contractor can be held liable under the FCA even if “the governmental entity decides that it should continue to fund the contract, *even though it finds that the contractor made a false statement in connection with a claim.*” *Id.* at 916 (emphasis added). However, this case too is inapposite as CMS was not aware of defendants’ false statements.

proposition that liability attaches when the claim is made, and is not dependant on any action that the government may or may not take upon receiving the claim (*i.e.* the materiality standard established by *Mylan*). Plaintiffs agree.

The cases defendants cite to support their proposition that plaintiffs cannot meet their burden of proving materiality are also inapposite. In *United States ex rel. Bennett v. Genetics & IVF Inst., Inc.*, No. 98-2119, 1999 WL 978881 (4th Cir. Oct. 28, 1999), the government sought a company to provide paternity testing for a new federally-funded program. The request for proposal (RFP), which became part of the contract, included the desired methodology to be used for the testing. *See id.* at *1. When bidding on the proposal, the defendant informed the government that it was using an alternative method, the government agreed that this method was acceptable and granted the contract to the defendant. *See id.* at *3. The court determined that there was no intent to defraud and that defendant's statements in the RFP were immaterial as they did not have the "natural tendency" of influencing agency action. *See id.* In the instant case, there was no such communication and certainly no active agreement by the government that defendants' false statements were acceptable.

In *United States v. Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003), the government had a contract with owners of an apartment complex granting them a private mortgage loan if they kept the property "in good repair and condition." *Id.* at 672. The government conducted numerous inspections which all showed that the property did not meet this standard and the government imparted this information regularly to defendants.

See id. at 673-74. The court, in a *concurring* opinion, found that the defendants' certifications to the government that their property was in good repair and condition were not material. *See id.* at 680. This case is also wholly inapposite to the present situation.

D.

Defendants' argument that FULs were "never intended to be set at a level that approximated a pharmacist's estimated acquisition cost" (FUL Thirteen Opp. at 7) is unsupported by law or record evidence, entirely false and absurd, particularly since this sort of "the government didn't care if our published prices reflected reality or not" argument has been repeatedly rejected by this court. *See, e.g., Mylan*, 608 F. Supp. 2d at 144; 95; *Track One Trial*, 491 F. Supp. 2d at 95; *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 173-4 (D. Mass. 2007) ("Defendants' interpretation that they have carte blanche to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results."); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass. 2006) (no evidence "that Congress intended to give the pharmaceutical industry free reign over drug pricing."). The regulations make clear that FUL was meant to be a cost savings device and cap on Medicaid reimbursements that otherwise were legally required to be at EAC. There is no support anywhere for the proposition that the FUL was meant to give drug companies a blank check for mega-spreads and to cause an increase in reimbursement to levels beyond EAC or any approximation of actual price.

In sum, plaintiffs have discharged their burden, and more, to show that “defendants submitted false prices that, if truthful, would likely have affected the [Federal Upper Limit] FUL.” *In re Pharm. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d 402, 405 (D. Mass. 2007) (“*NY Counties II*”); *see also* FUL Thirteen Opp. at 1.

II. DEFENDANTS’ ATTEMPT TO DISCREDIT PLAINTIFFS’ EXPERT IS UNAVAILING

The FUL Thirteen’s challenge to the alternative WACs and FULs presented by plaintiffs’ expert Harris Devor holds no water whatsoever. Plaintiffs address this completely in their opposition to defendants joint motion to exclude the proffered expert report and testimony of Harris Devor, C.P.A. For now, suffice it to say that, first, as noted above, defendants have presented no record evidence to support the veracity of their WACs. Second, whether Mr. Devor’s results may or may not track industry expectations is entirely irrelevant to the question of whether the WACs reported by defendants were accurate. There is a certain irony to this part of defendants’ argument given that (a) to the extent the “industry” includes Medicaid, the very fact of the instant lawsuit and the scores of other lawsuits filed by State AGs and the Federal Government reveals the reaction when payors realized that reality did not comport with what their expectations were. Payor expectations were that by reimbursing at WAC + or AWP – they were complying with federal law that required them to reimburse at EAC. When they learned the truth, they sued. Third, defendants do not make a single substantive criticism of Mr. Devor’s treatment of their data. There is no analysis whatsoever of Mr. Devor’s class of trade choices, treatment of rebate payments, chargeback payments, other

discounts, credits or incentives paid. Defendants complain that Mr. Devor uses proxies on certain occasions where the data reveals oddities. Proxies are a convention. Defendants' own expert uses them and explains that given the timing of chargebacks and rebates, it is not unusual to see negative results in a given quarter. (*See* Nov. 20, 2008 Deposition of Sumanth Addanki at 170:4-172:10, 174:20-176:9, 182:4-184:2, 184:10-185:18) (attached as Exhibit B to the Allen Aff.).²²

Defendants raise no protest to the actual math involved in Mr. Devor's calculation of alternative FULs based on prices at or about defendants' AMPs. Even if all other aspects of Mr. Devor's report and testimony are excluded (and they should not be of course), this part remains and, by itself, establishes the falsity of defendants' price reports.

Defendants say Mr. Devor's analysis is incomplete because he analyzed only 13% of the NDCs associated with the GCNs. That is irrelevant to plaintiffs' motion that seeks judgment that the FUL Thirteen's failure to submit accurate prices likely impacted the FUL and violated Section 145-b.

Defendants criticize Mr. Devor for not opining on what CMS would have done with true prices. Of course that is beyond Mr. Devor's (and Dr. Addanki's) expertise. CMS can speak for itself and has. *See generally* Gaston Decl. Ultimately, defendants cannot escape that fact that WACs were the basis for FULs (which defendants knew) and this Court has held that "[w]hen the defendants published false WACs, they insured that

²² Defendants complain about Mr. Devor's AWP's. They are not part of this motion.

any claims for reimbursement for their drugs would be false.” *See Mylan*, 608 F. Supp. 2d at 147.

CONCLUSION

For all the foregoing reasons, plaintiffs respectfully request that their motion for partial summary judgment be granted.

Dated: June 30, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT ON ISSUES RELATING TO THE FEDERAL UPPER LIMIT AND UNDER NEW YORK SOCIAL SERVICES LAW § 145-B, and Appendices A and B thereto to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

_____/s/
James P. Carroll, Jr.
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